# MISSOURI BOARD OF PHARMACY



# ANNUAL REPORT



FY 2022



Michael L. Parson, Governor State of Missouri

Chlora Lindley-Myers, Director Department of Commerce and Insurance

Sheila Solon, Division Director Division of Professional Registration



Michael L. Parson Governor State of Missouri

# Sheila Solon, Division Director DIVISION OF PROFESSIONAL REGISTRATION

Department of Commerce and Insurance Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY 3605 Missouri Boulevard P.O. Box 625 Jefferson City, MO 65102-0625 573-751-0091 PHONE 573-526-3464 FAX 800-735-2966 TTY Relay Missouri 800-735-2466 Voice Relay Missouri Kimberly A. Grinston Executive Director www.pr.mo.gov/pharmacists email: MissouriBOP@pr.mo.gov

To The Honorable Governor Michael L. Parson:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report which contains the proceedings of the Board for the fiscal year ending June 30, 2022 ("FY 22"). The Board's mission is to protect the public in the regulation of pharmacy practice. The Board of Pharmacy is pleased to report another successful year.

Respectfully Yours, MISSOURI BOARD OF PHARMACY

By:

Kimberly Grinston Executive Director



# Department of Commerce and Insurance Division of Professional Registration Missouri Board of Pharmacy

### FY 2022

#### **Board Members**

James Gray, PharmD., President
Christian Tadrus, PharmD., Vice-President
Colby Grove, PharmD., Member
Douglas Lang, R.Ph., Member
Christina Lindsay, PharmD., Member
Pamela Marshall, R.Ph., Member
Anita K. Parran, Public Member

#### Missouri Board of Pharmacy

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Kimberly A. Grinston, J.D., Executive Director

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### **Executive Summary**



This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2021 to June 30, 2022 (FY22). The Board is pleased to announce another successful regulatory year as reflected below:

#### **Board Operations**

- The Board held thirty-three (33) meetings during FY 22, including, eighteen (18) regular meetings, nine (9) email ballot meetings, (4) Board sub-committee meetings [Rx Cares Sub-Committee], and two (2) Pharmacy Working Conditions Task Force Meetings.\* In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held one (1) virtual meeting facilitated by the Board.\*
- Meeting totals were consistent with FY21 (30 meetings), however, FY22 meeting totals constitute a 57% increase from FY 18 and a 43% increase from FY 19. (The Board experienced an unprecedented number of meeting during FY 20 to address the initial stages of the COVID-19 pandemic.)
- As part of its ongoing efforts to protect patients through voluntary compliance, the Board hosted seven (7)
  educational webinars. Educational programs were free and Board approved for pharmacist continuing
  education.

#### Financial Overview

- The Board's total appropriation and authorized transfers for FY 22 were \$ 3,828,214.00. Board expenditures totaled \$ 2,804,764.80, representing a 10.8% increase from FY 21 attributable to increased Rx Cares for Missouri expenditures.
- Board revenue increased by 22.3% to \$3,025,317.18.

### Licensing Summary

- Total Board licensees/registrants remained consistent with 38,241 licensees/registrants at the close of the fiscal year (+2.1%), as reflected below:
  - o Drug Distributors (1,298, -2.8%)
  - o Drug Distributor Manufacturer Registrants (96, 4.9%)
  - o Drug Outsourcers (43, 4%)
  - o Intern Pharmacists (1,756, +3.3%)
  - Pharmacists- Active & Inactive (12,190, +4.3%)
  - o Pharmacists- Temporary (13, -7.4%)
  - Pharmacies (2,630, -1.23%)
  - o Pharmacy Technicians (20,010, +1.5%)
  - Third-party Logistics Providers (205, +7.3%)
- New licensees/registrations increased for the second consecutive fiscal year to 7,223 new licenses/ registrations issued (+ 8.6%).
- Total licensed pharmacies remained consistent with a slight 1.2% decline to 2,630 pharmacies licensed by the Board (1,471 in-state/1,159 non-resident). Currently, all Missouri counties have a licensed pharmacy with the exception of Schuyler county. Fifteen (15) Missouri counties only have one licensed pharmacy.

### **Complaint Handling**

- The Board received/opened 697 new complaints in FY 22, representing a 49% increase from FY21. One (1) tax compliance case/complaint was referred from the Missouri Department of Revenue during FY 22, although tax compliance cases have been significantly higher in prior fiscal years.
- The Board issued final dispositions on 562 complaints/cases in FY22, which was consistent with FY 21

# **Executive Summary**



(574 complaints/cases).

 Five-hundred and sixty-one (561) of closed complaints/cases were non-tax related; One (1) tax related judicial complaint/case was closed during the fiscal year.\* Of the 561 non-tax related complaint dispositions, 86% resulted in no disciplinary action (484 cases), while disciplinary action was taken in the remaining 14% (78 cases).

#### **Disciplinary Actions**

• The Board issued seventy-eight (78) practice related disciplinary actions in FY 22, representing a 10% increase from FY21. Despite the increase, total Board discipline remained historically lower.

### Inspections/Investigations

- The Board continued a modified inspection schedule in FY 22 due to COVID-19, with limited inspections of high risk facilities (e.g., long-term care, infusion/chemotherapy facilities)
- Under the modified inspection schedule, 1,081 regulatory inspections were conducted which was consistent with FY 21 (1,073 inspections).
- Despite COVID-19 restrictions, total completed investigations increased by 27% to 262 completed investigations, which aligns with pre-pandemic totals.

#### Compounded Drug Testing

 Pursuant to § 338.150, RSMo, the Board conducts a testing program for drug preparations compounded by licensed pharmacies. 87% of products tested in FY22 were satisfactory while 13% were unsatisfactory. Failing potency results ranged from 82.5% to 111.1%.

### Rulemaking

- The Board continued its review of Missouri's pharmacy rules to ensure appropriate and consistent regulation and prompt access to care.
- Eight (8) administrative rules were adopted or amended in FY 22, including four (4) COVID-19 related emergency rule amendments. The Board submitted one (1) legislative proposal for approval by the Governor to clarify/expand authorized pharmacist services to address a public health need or a declared public health emergency

#### Rx Cares for Missouri

- The Board expended \$ 233,205.92 for the Rx Cares for Missouri Program in FY 22, with \$ 211,320.85 in Rx Cares grant funding and Rx Cares educational activities, and \$27,975 for the Rx Cares medication destruction/disposal program.
- One-hundred and ten (110) entities participated in the medication destruction/disposal program in FY 22, including, pharmacies, hospitals, and local law enforcement agencies.
- Approximately 11,198 pounds of unwanted medication was destroyed in FY22 under the Rx Cares Medication destruction program. Approximately 16,864 pounds of unwanted medication have been destroyed since initial program implementation in FY 20 (@ 8.4 tons).

### About the Board



#### Mission Statement

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- Licenses only qualified and competent professionals, and;
- Ensures compliance with professional standards and federal and state pharmacy law.

#### ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Commerce and Insurance.

#### **MEMBERSHIP**

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

#### **FUNCTIONS**

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies, drug distributors, drug outsourcers and third-party logistics providers;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/ registrant;
- Inspection of pharmacies, drug distributors, drug outsourcers and third-party logistics providers; and
- Approval of preceptors and intern training facilities.

### **Board Operations**

#### **General Board Operations**

The Board held thirty-three (33) meetings during FY 22, including, eighteen (18) regular meetings, nine (9) email ballot meetings, (4) Board sub-committee meetings [Rx Cares Sub-Committee], and two (2) Pharmacy Working Conditions Task Force Meetings.\* In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held one (1) virtual meeting facilitated by the Board.\*

\*Due to the COVID-19 pandemic, public members were able to access and virtually attend open session meetings.

#### **Staff**

The following staff were employed by the Board at the close of FY22:

#### Staff

- Kimberly Grinston, J.D., Executive Director
- Jennifer Boehm, Administrative Coordinator
- Vacant, Pharmacy Technician Coordinator
- Jason Menken, Compliance Coordinator
- Vacant, Pharmacy/Drug Distributor Coordinator
- Linsey Acs, Pharmacist Coordinator
- Jasmine Whittier, Pharmacist Coordinator

#### Inspectors

- Tom Glenski, R.Ph., Chief Inspector
- Bennie Dean, R.Ph.
- Katie DeBold, PharmD.
- Andrea "Andi" Miller, PharmD.
- Scott Spencer, R.Ph.
- Lisa Everett, R.Ph.
- Daniel Vandersand, R.Ph.
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

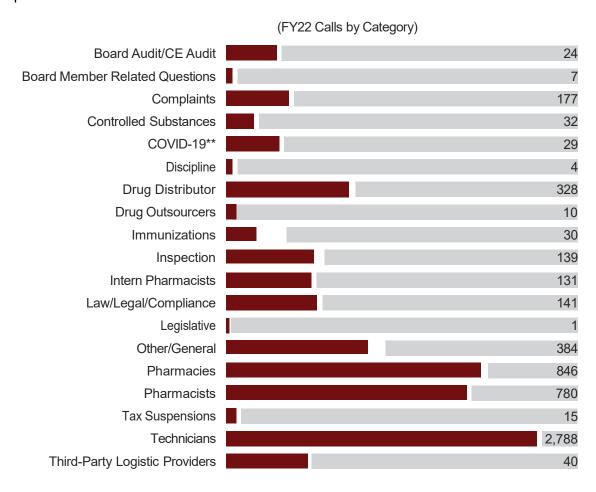
# **Board Operations**



#### Office Activities

The Board received/responded to 5,906 telephone calls during FY 22, representing a 10% decrease from FY 21.

Major call topic areas are identified below:



<sup>\*</sup> Pharmacist category includes licensing, continuing education and audit related questions.

<sup>\*\*</sup>COVID-19 related calls may have also been recorded in other categories (e.g. Law/Legal/Compliance/Immunizations/Pharmacy/etc.

# **Board Operations**



### **Education/Training**

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following compliance webinars in FY 22 (participants were awarded free continuing education credit):

- 2021 Legislative Update
- 2021 Pharmacy Technician Update
- 2021 Compliance Update/Inspector Q&A
- 2021 How Are You? Pharmacy Well-Being, Mental Health, and Suicide Awareness
- 2022 COVID-19 Update
- 2022 BNDD Update
- 2022 Pharmacist Administration Update

#### Legislative Proposals

The following legislative proposal was approved by the Board for the 2022 legislative session:\*\*

 Emergency Response Authority: Allows pharmacists to order and administer medication as approved or authorized by the U.S. Food and Drug Administration (FDA) to address a public health need during a state/federally declared public health emergency, or as authorized by the Missouri Department of Health and Senior Services to address a public health need.

#### **Gold Certificates**

The following individuals received Gold Certificates during FY 22 representing fifty (50) years of licensure as a Missouri pharmacist:

- James M. Arnott
- James L. Barnes
- Mark J. Beckwith
- Dennis R. Bond
- Charles W. Bond
- Bernard J. Bristow
- James A. Cordes
- Roy H. Eberhart II
- John R. Flow
- Donald W. Grove Jr.
- Tedd H. Kimelman
- Robert D. Lewis
- Wayne R. Muentnichs
- Russell U. Nesbitt Jr.
- George L. Oestreich
- Gail Orr
- John C. Resch
- Benjamin M. Tally Jr.
- Thomas R. Wooten

<sup>\*\*</sup> Section 324.035 was enacted in FY 20 which prohibits professional/occupational boards within the Division of Professional Registration from using Board funds to provide designated continuing education classes.

<sup>\*\*</sup> Legislative proposals are subject to Governor approval.

# **Financial Summary**



#### Financial Overview:

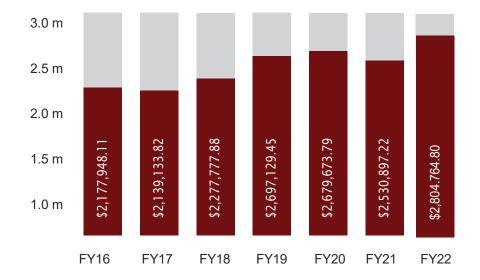
The Missouri Board of Pharmacy's appropriation for the fiscal year ending June 30, 2022, was as follows:

Personal Service \$ 1,251,634.00
Expense and Equipment \$ 1,419,530.00
Criminal History Fund \$ 5,000.00
Transfers\* \$ 1,152.050.00
\$ 3,828,214.00

Of the amount appropriated, the Board expended \$ 2,804,764.80 in FY 22 as follows:

Personal Service \$ 1,231,375.47 (44%) Expense and Equipment \$ 580,462.91 (20.6%) Transfers\* \$ 992,926.42 (35.4%)

FY 22 expenditures represent a 10.8% increase from FY 21 attributable to increased expenditures for the Rx Cares for Missouri Program.



<sup>\*</sup>Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.

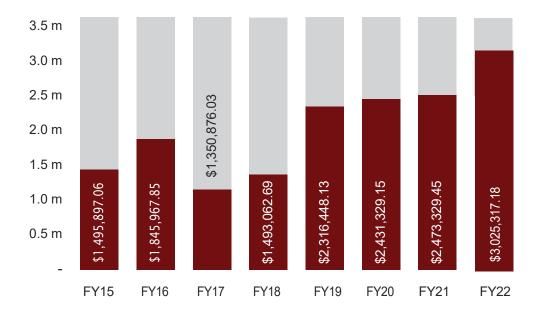
# **Financial Summary**



#### Revenue Received:

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that revenue produced does not substantially exceed the cost and expense of administering Chapter 338.

Board revenue increased in FY 22 by 22.3% which may be attributable to an increased number of licensees returning to the pharmacy workforce after the height of the COVID-19 pandemic. The Board will continue to monitor future revenue trends to ensure compliance with § 338.070, RSMo.





### **Licensing Summary**

Pursuant to Chapter 338, RSMo, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies, drug distributors, drug outsourcers and third-party logistics providers.

The Board's total licensee/registrant count remained consistent with 38,241 licensees/registrants at the close of the fiscal year (37,929 active/312 inactive), as reflected below:

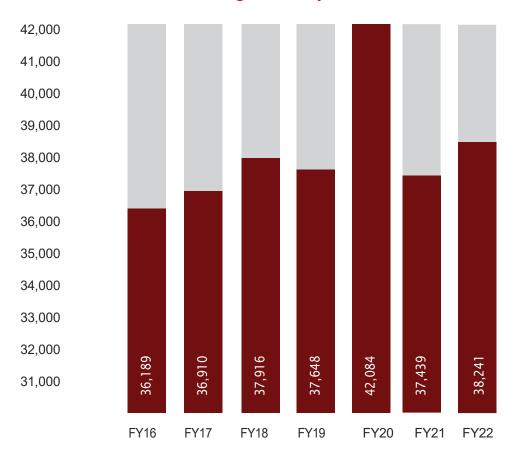
LICENSING TOTALS						
Drug Distributors (licensed & temporary)	1,298 (-2.8%)					
Drug Distributor Manufacturer Registrants	96 (-4.9%)					
Drug Outsourcers	43 (- 4%)					
Intern Pharmacists	1,756 (+3.3%)					
Pharmacists (active and inactive)	12,190 (+4.3%)					
Pharmacists (temporary)	13 (-7.4%)					
Pharmacies (instate, non-resident and temporary)	2,630 (-1.23%)					
Pharmacy Technicians	20,010 (+1.5%)					
Third-Party Logistics Provider (licensed & temporary)	205 (+7.3%)					
TOTAL	38,241 (+2.1%)					

While total license counts remained stable, new licensees/registrations increased for the second consecutive fiscal year to 7,223 new licenses/ registrations issued in FY 22 (+ 8.6%), as reflected below:

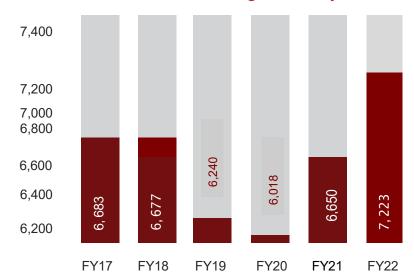
- Drug Distributors (129, +44.9%)
- Drug Distributor Registrants (5, +25%)
- Drug Outsourcers (5, -28.5%)
- Intern Pharmacists (368, -23.8%)
- Pharmacies (210, -14.8%)
- Pharmacists (Active and Inactive) (513, +17.6%)
- Pharmacy Technicians (5,949, +11.59%)
- Temporary Pharmacists (10, -9%)
- Third-Party Logistics Providers (34, +3%)



### Total Licensees/Registrants by Fiscal Year



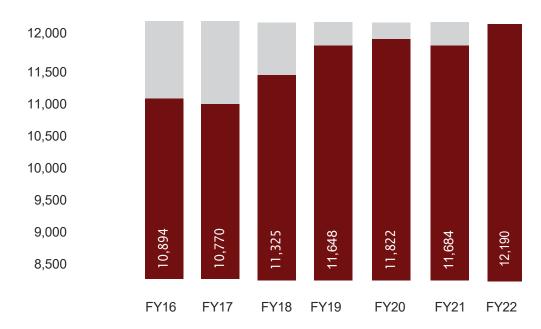
### New Licensees/Registrants by FY





#### Pharmacists:

Total licensed pharmacists increased by 4.3%, reversing a minor decline in FY 21:



Active vs. inactive Missouri pharmacists are reflected below (resident and non-resident):

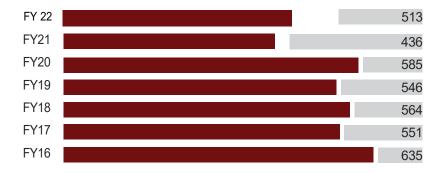
Active Licensees	11,878
Inactive Licensees	312
TOTAL LICENSED PHARMACISTS	12,190

<sup>\*\*</sup>Inactive pharmacists are not authorized to practice in Missouri but remain licensed. Pharmacists may only go inactive during the renewal period.



#### Number of New Pharmacist Licenses Issued

Newly licensed pharmacists increased by 17.6%, reversing a 25.4% decline in FY 21 likely attributable to COVID-19 and related state/federal allowances authorizing non-resident pharmacists to provide designated emergency/immunization services in Missouri without a Missouri pharmacist license:



#### Pharmacists Residing in Missouri

No significant changes occurred in actively licensed resident vs. non-resident pharmacists. Approximately 60.4% of pharmacists reported a Missouri address as reflected below:

Resident Pharmacists	7,176
Non-Resident Pharmacists	4,702
Total Missouri Resident Pharmacists	11,878

#### Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines pursuant to a protocol with a Missouri-licensed physician, upon filing a Notification of Intent with the Board. At the end of FY 22:

- 3,605 pharmacists were authorized to administer medication by prescription, representing a 10.6% increase from FY 21.
- 4,025 pharmacists were authorized to administer immunizations by protocol, representing a similar 10.7% increase.

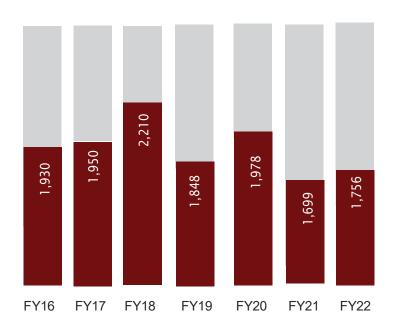
#### **Medication Therapy Services:**

Section 338.010, RSMo, authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 3,734 pharmacists held a MTS certificate at the end of FY 22, representing a 46% increase from FY21.

#### Intern Pharmacists

Total intern pharmacists increased by 3.3%, while new intern pharmacists decreased by 23.8% (368 new licensees). The decrease in new interns corresponds with the national decline in pharmacy school students, which constitute the majority of intern pharmacists.

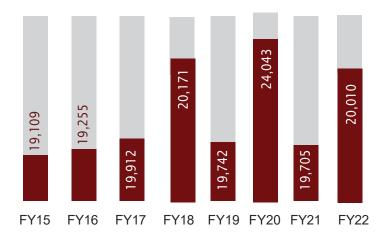






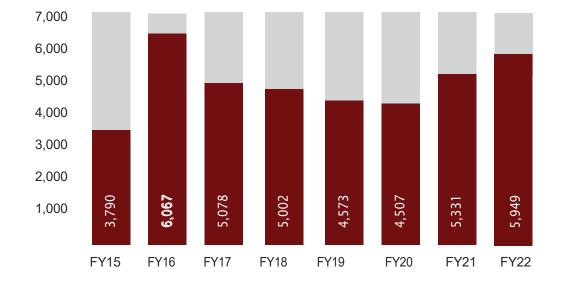
#### **Pharmacy Technicians**

Registered pharmacy technicians increased by 1.5%, likely attributable to pharmacy technicians returning to the work force after COVID-19 and increased pharmacy recruiting efforts to address staffing shortages. The FY 22 increase reverses the 18% decrease in FY 21 and aligns technician registration totals with historical licensing data.



### New Pharmacy Technician Registrations Issued

New pharmacy technician registrants increased for the second consecutive fiscal year by 11.5%.



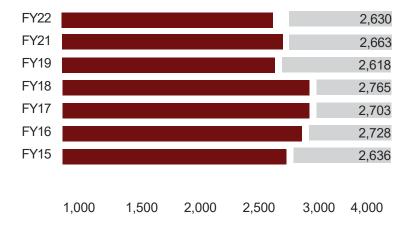


### **Pharmacy Summary:**

PHARMACY PERMIT TOTALS					
Instate Pharmacies	1,471				
Non-Resident Pharmacies	1,159				
Temporary Pharmacies	5				
TOTAL	2,630				

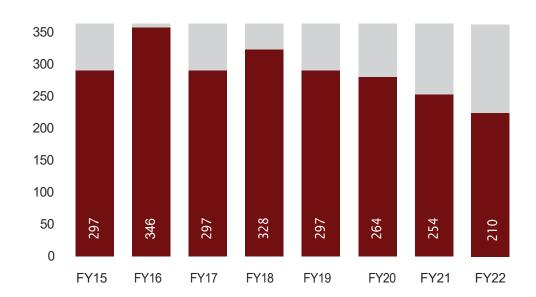
Total pharmacies remained consistent (both in-state and non-resident) with a minor 1.2% decline.

### Pharmacy Permitholders By Fiscal Year



### **New Pharmacy Permits Issued**

New pharmacy permits decreased by 17%, representing the 4th consecutive fiscal year with a decline.





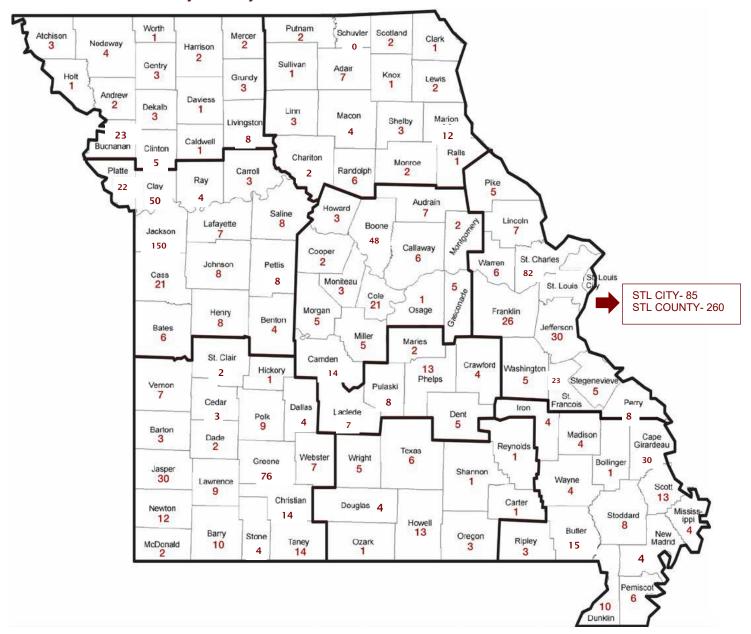
### Pharmacy Permits by Classification\*

(The totals below will not equal the total # of licensed pharmacies. Pharmacies may hold multiple classifications and could be reflected in more than one category).

(Pharmacies by Classification)					
Class A: Community/Ambulatory	2,100				
Class B: Hospital Pharmacy	164				
Class C: Long-Term Care	931				
Class D: Nonsterile Compounding	762				
Class E: Radiopharmaceutical	33				
Class F: Renal Dialysis	11				
Class G: Medical Gas	11				
Class H: Sterile Compounding	360				
Class I: Consultant Services	21				
Class J: Shared Services	1,276				
Class K: Internet	47				
Class L: Veterinary	61				
Class M: Specialty (Bleeding Disorder)	128				
Class N: Automated Dispensing System (Health Care Facility)	27				
Class O: Automated Dispensing System (Ambulatory Care)					
Class P: Practitioner Office/Clinic					
Class Q: Charitable Pharmacy					
Class R: Remote Dispensing Site Pharmacy	8				



### Missouri Pharmacies by County



#### Statistics to Note:

- Schuyler County is the sole Missouri county without a licensed pharmacy.
- Fifteen (15) counties have only (1) licensed pharmacy: Bollinger, Caldwell, Carter, Clark, Daviess, Hickory, Holt, Knox, Osage, Ozark, Ralls, Reynolds, Shannon, Sullivan, and Worth
- Sixteen (16) counties/areas declined in licensed pharmacies:
  - Buchanan (-1)\*
  - Butler (-1)
  - Camden (-1)
  - Cape Girardeau (-2)
  - Cedar (-1)



- Christian (-1)\*
- Clay (-3)
- Laclede (-1)
- Macon (-1)
- Pettis (-1)
- Ray (-1)
- St. Clair (-1)
- St. Charles (-5)
- St. Louis County (-3)
- Schuyler (-1)
- Stone (-1)

<sup>\*</sup>Counties also declined in FY 21.

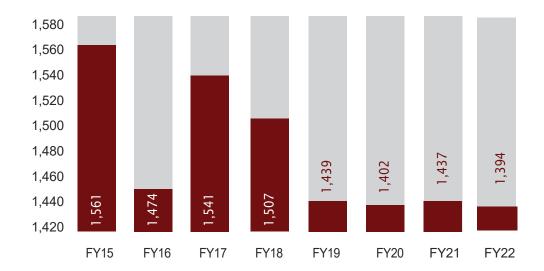


### **Drug Distributor Summary:**

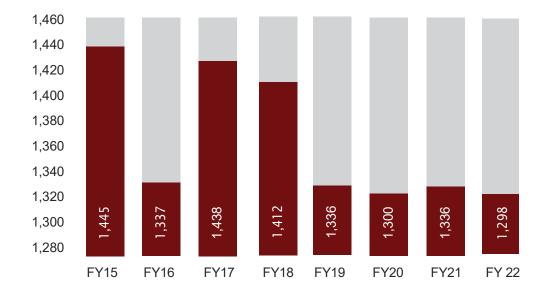
All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug related devices into Missouri must hold a Missouri drug distributor license.

#### TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR

Total licensed drug distributors and drug distributor registrants remained consistent with a slight 2.9% decrease (1,298 drug distributors and 96 drug distributor registrants).



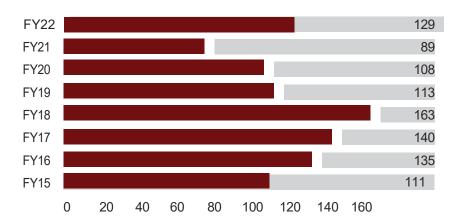
#### TOTAL DRUG DISTRIBUTORS BY FY





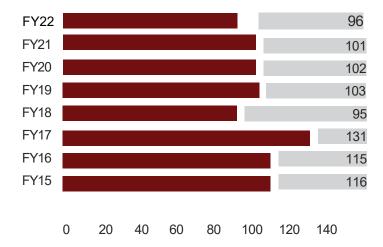
#### NEW DRUG DISTRIBUTORS LICENSED

Newly licensed drug distributors increased by 44.9%, representing the first increase since FY 18:



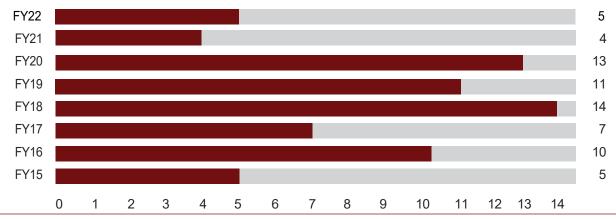
#### TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY

Total drug distributor registrants remained consistent:



#### NEW DRUG DISTRIBUTOR REGISTRANTS

The number of new drug distributor registrants remained historically low:





#### DRUG OUTSOURCERS/THIRD-PARTY LOGISTICS PROVIDERS

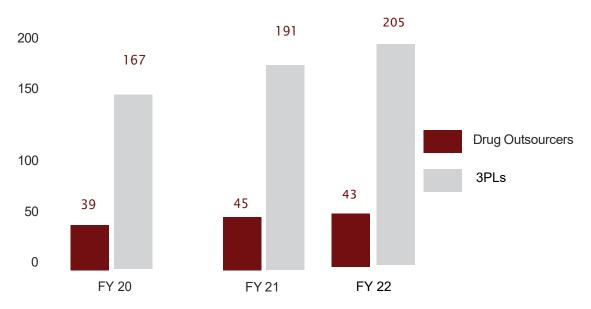
The Board began issuing drug outsourcer and third-party logistics provider (3PL) licenses in the fall of 2018

- Total 3PL licensees remained consistent [FY 21 (191); FY 22 (205)]
- Total drug outsourcer similarly remained consistent [FY 21 (45); FY 22 (43)]

New applicants for both license classes remained historically low:

- New 3PL licensees [FY 21 (33); FY 22 (34)]
- New drug outsourcer licensees [FY 21 (7); FY 22 (5)]

#### DRUG OUTSOURCERS / 3PL TOTALS



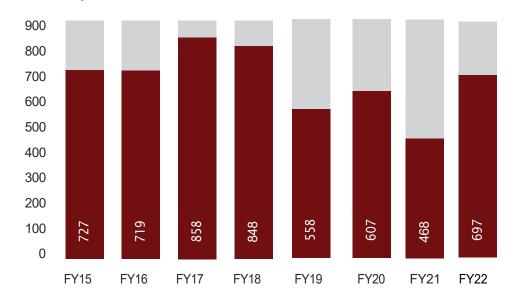
# **Complaint Summary**



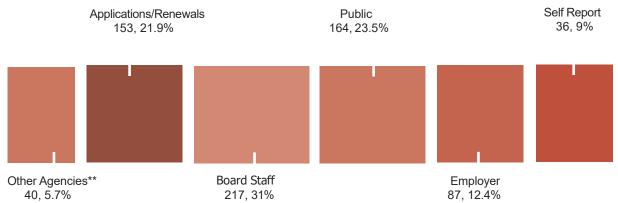
### **Complaint Summary**

All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 697 new complaints in FY 22, representing a 49% increase from FY21. Only one (1) tax compliance case/complaint was referred from the Missouri Department of Revenue during FY 22, although significantly higher in prior years.

#### Complaints Handled by FY



### Complaints by Source



# **Complaint Summary**



### FY22 COMPLAINTS BY CATEGORY

Adulterated Drugs	1
Advertising or Marketing	2
Audit	95
Compounding	11
Confidentiality	9
Criminal History	21
Disciplinary Action in Another State	96
Dispensing Error	43
Drug Distribution	2
Drug Diversion	18
Drug Losses	11
Expired Drugs in Active Inventory	1
Fraudulent Prescription	3
Fraud - Unspecified	4
Immunization/Administration	28
Impairment/Addiction	19
Improper Controls	50
Improper/Unauthorized Dispensing	55
Inspection Violations	8
Insurance Fraud	6
Licensure Applicant	94
Mandatory Reporting Violation	5
Misbranding	2
Other	9
Prescription Transfers	1
Recordkeeping	10
Sale of Drugs for Illegal Purposes	1
Sexual Misconduct	4
Tax Suspensions (Dept. of Revenue/Missouri Courts)	1
Theft (Non-drug)	26
Unlicensed Activity	36
Unprofessional Conduct	22
Violation of Discipline	3
TOTAL	697

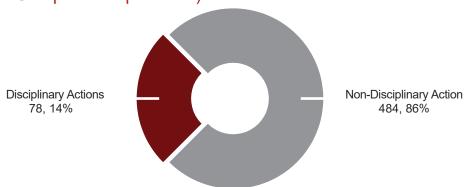
### **Complaint Summary**



#### COMPLAINT DISPOSITIONS

The Board issued final dispositions 562 complaints/cases in FY22, which was consistent with FY 21 (574 complaints/cases). 561 closed complaints/cases were non-tax related; One (1) tax related judicial complaint/case was closed during the fiscal year.\*

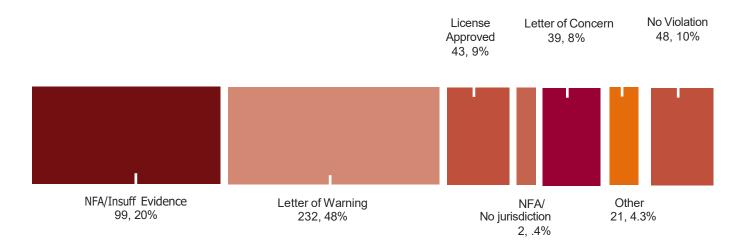
#### (Non-Tax Related Complaint Dispositions)



<sup>\*\*</sup>Complaint dispositions includes complaints received in prior fiscal years but finally determined in FY 22. As a result, complaint dispositions in FY22 will not equal the number of new complaints received.

#### SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 484 non-tax related complaints closed without disciplinary action in FY 22 (see Disciplinary Action section for complaints closed with disciplinary action):

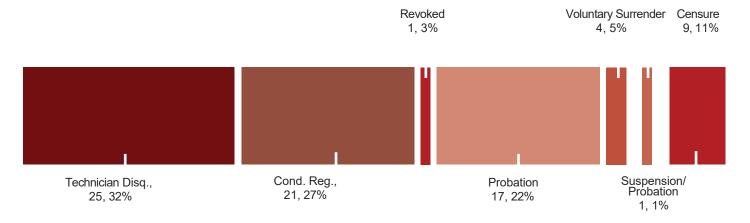


<sup>\*</sup> Other: Closed (9), Closed but Flagged for Future Review (10), Closed-Request Denied (1), Referred to Other Bd/Agency (1).



### **Summary of Disciplinary Action**

The Board issued seventy-eight (78) practice related disciplinary actions in FY 22, representing a 10% increase as reflected below:



### **DISCIPLINARY ACTIONS BY CATEGORY**

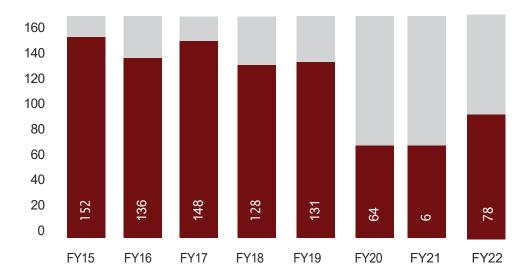
Drug Distributors Probated	3
Drug Distributors Censured	1
Drug Distributor Registrant Probated	1
Pharmacist Licenses Censured	6
Pharmacist Licenses Probated	6
Pharmacist Licenses Revoked	1
Pharmacist Licenses Suspended Followed by Probation	1
Pharmacist Licenses Voluntarily Surrendered (Treated as Discipline)	4
Pharmacy Permits Censured	2
Pharmacy Permits Probated	7
Technicians Disqualified	25
Technicians Placed on Conditional Employment	21
TOTAL	78



#### PRACTICE RELATED DISCIPLINARY ACTIONS \*

Forty-six (46) pharmacy technicians, 18 pharmacists, 9 pharmacies, 4 drug distributors and 1 drug distributor registrant, were disciplined for practice-related issues during FY 22. Total disciplinary actions increased by 10%, however, disciplinary actions continued to remain historically lower.

#### (Total Practice-Related Disciplinary Actions by FY)

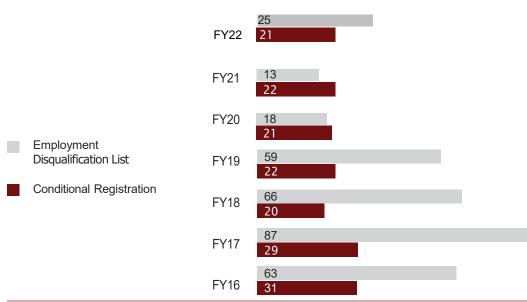


<sup>\*</sup> Does not include tax suspensions pursuant to § 324.010, RSMo.

#### PHARMACY TECHNICIAN DISCIPLINE

Forty-six (46) pharmacy technicians were disciplined for practice-related reasons, comprising 58.9% of all practice-related disciplinary actions issued by the Board.

#### (Practice Related Pharmacy Technician Discipline by FY)





# GROUNDS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION (Cause for EDL / # Disciplined)

- Criminal History (7)
- Diversion/Attempted Diversion (10)
- Misconduct (Non-Dispensing) (1)
- · Misconduct/Unauthorized Dispensing (1)
- Theft (Non-Drug Related) (6)

# GROUNDS FOR TECHNICIAN CONDITIONAL REGISTRATION (Cause for CR/ # Disciplined)

- Confidentiality/HIPAA Violation (1)
- Criminal History (9)
- Diversion (2)
- Illegal Drug Usage/Positive Drug Test (2)
- Theft (Non-Drug Related) (3)
- Theft/Refused Drug Test (1)
- Unlicensed Activity (2)
- Unlicensed Activity/Violation of Discipline (1)

#### PHARMACIST DISCIPLINE BY FY:

Pharmacist practice-related discipline remained consistent with eighteen (18) pharmacists disciplined in FY 22. Significantly, the total number of disciplined pharmacists represents less than 0.14% of Missouri-licensed pharmacists at the close of FY 22.

	FY16	FY17	FY18	FY19	FY20	FY21	FY22
Censure	6	6	3	11	5	2	6
Probation	14	13	15	10	6	8	6
Suspension	0	0	0	0	0	0	0
Suspension/Probation	4	0	1	0	2	5	1
Revocation	3	1	1	1	2	1	1
Voluntary Surrender (treated as discipline)	1	4	1	4	1	2	4
TOTAL	27	24	21	26	16	18	18



#### PHARMACY DISCIPLINE BY FY

Pharmacy discipline increased by 50% as reflected below, although total disciplinary actions remained historically low:

	FY16	FY17	FY18	FY19	FY20	FY21	FY22
Censure	4	0	4	0	1	0	2
Probation	8	7	9	15	5	6	7
Revocation	2	0	0	0	0	0	0
Voluntary Surrender	0	0	2	1	2	0	0
TOTAL	14	7	15	16	8	6	9

### DRUG DISTRIBUTOR DISCIPLINE BY FY

Total drug distributor/drug distributor registrant disciplinary actions remained historically low, as reflected below:

	FY16	FY17	FY18	FY19	FY20	FY21	FY22
Censure	0	0	0	0	0	0	1
Probation	1	0	4	6	1	3	3
Voluntary Surrender	0	0	0	0	0	0	0
TOTAL	1	0	4	6	1	3	4

# Inspections/Investigations

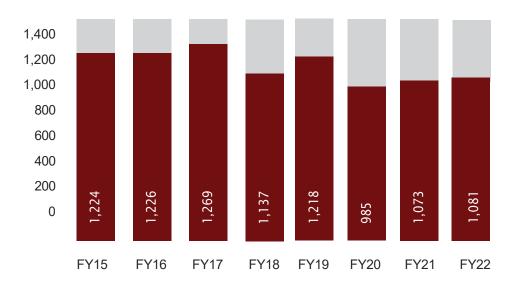


### Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies, drug distributors, drug outsourcers and third-party logistics providers. Board inspectors also conduct investigations as assigned.

- The Board continued a modified inspection schedule as part of its COVID-19 precautions, with limited inspections of COVID-19 high risk facilities during a portion of the fiscal year (e.g., long-term care, infusion/chemotherapy facilities)
- Under the modified inspection schedule, 1,081 regulatory inspections were conducted during the fiscal year. The Board anticipates returning to a full inspection schedule in FY23.
- 883 pharmacies, 182 drug distributors, and 16 third-party logistics providers were inspected during the fiscal year. Fifteen (15) drug distributors were exempt from inspection as state facilities or as authorized by 20 CSR 2220-5.040 for facilities inspected by the U.S. Food and Drug Administration.
- Despite COVID-19 restrictions, total completed investigations increased by 27% (262 investigations), aligning investigations with pre-pandemic totals.

#### Pharmacy/Drug Distributor Inspection Summary



#### INSPECTION FINDINGS

At the conclusion of an inspection, an inspector may initiate one of the following resolutions:

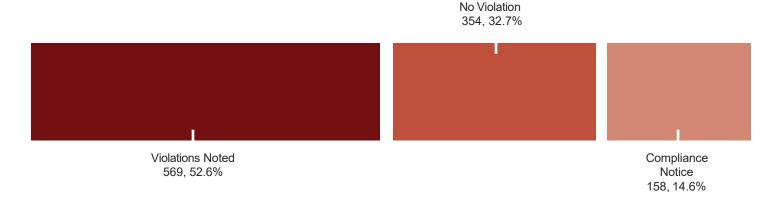
- Observation Report: Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- Compliance Notice: Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- Quality Assurance Report: Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- Investigation: An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.

# Inspections/Investigations



#### **FY22 INSPECTION RESULTS\***

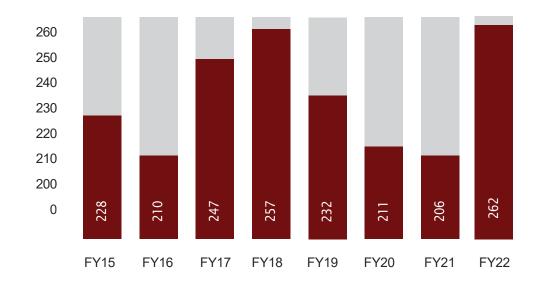
Approximately 67% of Board inspections resulted in violations noted or a compliance notice being issued as reflected below:



Inspection results in each category remained statistically consistent (e.g., no violation, violations noted, compliance notices).

#### FY 22 INVESTIGATION SUMMARY

Despite COVID-19 precautions, total completed investigations increased by 27% to 262 completed investigations, which aligns with pre-pandemic totals.



<sup>\*</sup> Includes inspection results for follow-up inspections and investigations.

# **Compounded Drug Testing**



### **Testing Summary**

Pursuant to § 338.150, RSMo, the Board operates a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2022:

Dosage Form	Tests Performed
Capsule	20
IV Solution	1
Injection	3
Topical Spray	2
Ophthalmic Solution	1
Oral Solution	1
Oral Suspension	9
Tablet	1
Topical Cream/Ointment/Gel	7
Vaginal Capsule	1

Test Results	Tests Performed	Percentage	
Satisfactory	40	87.0%	
Unsatisfactory	6	13.0%	
Total	46	100%	

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 82.5% to 111.1%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

Preparations With Unsatisfactory Results		
5-Fluorouracil/Salicylic Acid		
Hydrocortisone		
Ivermectin		
Lidocaine HCl/Tetracaine HCl		
Naltrexone		
Rifampin		

### Rulemaking



### **Rule Changes**

The Board continued its ongoing review of Board rules to ensure appropriate and consistent regulation and to adopt a standards of practice approach that is focused on:

- · Establishing standards of practice to ensure patient safety
- Eliminating unnecessary regulatory requirements, and
- Maximizing pharmacist skill, training and education to enhance patient access to care.

The following rules were promulgated/amended by the Board in FY22:

(Rescinded & Repromulgated)  20 CSR 2220-2.200 (Emergency & Proposed)  20 CSR 2220-2.200 (Emergency-Feb. 2022)  20 CSR 2220-2.400 (Emergency)	clared Disasters	Updated and streamlined allowances for pharmacies to provide pharmacy services during a declared or natural disaster.  Removed requirement for duplicate Risk Level 3 sterility/endotoxin testing to prevent medication shortages  Allowed portability of aseptic technique skill assessments for pharmacy staff subject to
(Emergency & Proposed)  20 CSR 2220-2.200 Ster (Emergency-Feb. 2022)  20 CSR 2220-2.400 Com (Emergency)		Level 3 sterility/endotoxin testing to prevent medication shortages  Allowed portability of aseptic technique skill assessments for pharmacy staff subject to
(Emergency-Feb. 2022)  20 CSR 2220-2.400 (Emergency)  20 CSR 2220-2.425 Req	rile Compounding	assessments for pharmacy staff subject to
(Emergency)  20 CSR 2220-2.425 Req		Board requirements, to address COVID-19 related staff shortages.
	npounding Standards of Practice	Allowed pharmacies to compound iodinated contrast media for other hospitals, pharmacies, practitioners, or entities in advance of a patient specific prescription to address a national shortage
(Now)	uired Pharmacy Reporting	Established reporting requirements for pharmacy compounding data to implement federal law/requirements.
	ndards of Operation for a Class J: red Services Pharmacy	Updated Class J requirements to increase patient access to care via a pharmacy shared services arrangement; Removed Class J licensure requirements for designated long-term care shared services.
Annual Report		36

# Rulemaking



20 CSR 2220-2.685 (New)	Standards of Operation for a Class Q: Charitable Pharmacy	Implemented licensure for Class Q Charitable pharmacies & established operational standards.
20 CSR 2220-2.725 (Emergency & Proposed)	Remote Data Entry	Allowed remote data entry from a U.S. location/Removed Missouri only location requirement.



#### **Rx Cares Program Overview**

The Missouri General Assembly enacted § 338.710 in 2017 which created the Rx Cares for Missouri Program within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri. The following program activities occurred in FY22:

#### **Rx Cares Medication Destruction Program**

The Rx Cares program was enacted simultaneously with § 338.142, RSMo, which granted the Board authority to establish a drug take-back program for controlled substances, in consultation with the Missouri Department of Health and Human Services. The Board subsequently established the statewide Rx Cares for Missouri Medication Destruction and Disposal Program for the collection of unused/unwanted medication. The medication destruction/disposal program plays a critical role in combatting the opioid epidemic by providing safe options for patient disposal of unused or unwanted medication.

Pursuant to state contract, the medication destruction/disposal program is managed/operated by Sharps Compliance® under the supervision of the Board. Eligible program participants include:

- A licensed Missouri pharmacy or drug distributor
- A licensed healthcare provider authorized to prescribe controlled substances
- · A hospital, office, clinic, or other medical institution that provides health care services
- A federal, state, local, or municipal public health, law enforcement, or other governmental agency, or
- A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education. [20 CSR 2220-2.990]

Board approved program participants are provided a medication collection receptacle that complies with state and federal controlled substance laws. Collected medication can be mailed/ submitted to an approved Sharps Compliance® vendor up to twelve (12) times per year at no cost to the participant.

- Expenditures for the medication destruction/disposal program totaled \$ 27,975 in FY 22
- One-hundred and ten (110) entities participated in the medication destruction/disposal program in FY
   22, including, pharmacies, hospitals, and local law enforcement agencies
- Approximately 11,198 pounds of unwanted medication was destroyed in FY22
   Approximately 16,864 pounds of unwanted medication have been destroyed since initial program implementation in FY 20 (@ 8.4 tons)



### **Rx Cares Grant Program**

Section 338.710, authorizes the Board to expend, allocate or award funds appropriated to the Board to provide programs or education to promote the Rx Cares Program goals. The following Rx Cares grant funding was awarded in FY 22:

Recipient	Description	Funding Amount
Alps Pharmacy	Providing Dispill adherence packaging to patients to facilitate medication adherence and prevent medication errors	\$ 11,823
Butler Drug Store	Rescue MO Lives Educational Program: Goal is to decrease the # of patients suffering from opioid abuse and misuse in Southeast Missouri by providing patient education on safe opioid use/practices and naloxone.	\$ 13,466.20
MO HealthNet Division	Funding awarded for the "Safe at Home" medication disposal initiative, in partnership with the Missouri Department of Health & Senior Services (DHSS), MO HealthNet Division.  Effective January 15, 2022, grant funding available to reimburse eligible MO HealthNet pharmacy providers who dispense at-home medication disposal packets to MO HealthNet participants at risk of experiencing an opiate-related overdose	\$ 100,000
Prevention Consultants	Safe medication and opioid abuse training for youth and adults in Crawford, Dent, Gasconade, Iron, Maries, Phelps, St. Francois and Washington Counties	\$ 25,000
Rhonda Bilger	Brentmoor Retirement Community intervention and pharmacist education program for elderly patients	\$ 11,893
Ste. Genevieve Community Services Forum	Community and student drug safety educational program. Program activities include: (1) "Stop the Stigma" educational initiative, (2) prevention educational activities for ages 9-12, and (3) August 2023 substance awareness conference, (4) facilitation of drug take-back programs, and (5) collaboration with Ste. Genevieve County Memorial Hospital to monitor/trend benzodiazepine and opiate prescriptions.	\$ 24,991.65
Taney County	Taney County Alcohol and Drug Abuse Prevention Team (ADAPT). Youth focused safe medication, storage and usage program. Program operated in collaboration with UMKC pharmacy school, law enforcement agencies, and Community Partnership of the Ozarks.	\$ 24,146
	TOTAL AWARDED GRANT FUNDING	\$ 211,320.85



In addition to Rx Cares grant funding, the Board conducted a statewide patient safety educational campaign in February and March 2022, to educate and encourage patients to consult with their pharmacists on a variety of safe medication topics, including, safe opioid use and overdose prevention, medication review and consultations, vaccine needs and availability, safe medication disposal, care management, over-the-counter medication usage, and smoking cessation.

The patient safety campaign was coordinated by Hubbard & Associates, the approved state public relations vendor, and included targeted digital displays, social media advertising (Facebook & Instagram), and e-mail marketing. The public relations campaign specifically sought to re-engage patients who were unable to visit or



interact with their pharmacies/local pharmacist during the COVID-19 pandemic, with an emphasis on individuals aged 65 and older. Significantly, many of these patients may have experienced medication or health changes during the pandemic, or missed needed vaccines or health monitoring due to pandemic related restrictions/closures.

- The paid social media campaign reached 1,081,762 unique individuals; 3,321,394 social media ads were served
- 2,933,915 targeted display impressions were served, resulting in 7,043 clicks to the Board's custom Rx Cares medication safety webpage
- 202,218 targeted e-mail messages were sent resulting in 52,729 unique views

### **Rx CARES FOR MISSOURI FY 22 FINANCIAL SUMMARY**

#### FY 22 Appropriation

Legislative Appropriation Adjustments/Refunds

**Total Funding** 

\$	750,000.00	
\$	-	
		\$ 750,000.00

#### Funds Expended\*\*

Grant- Community Foundation of the Ozarks

**Grant- Prevention Consultants** 

Grant- Rhonda Bilger (Brentmoor Retirement Community)

Grant- Ste. Genevieve Community Services Forum

Hubbard Radio St. Louis (PR Campaign)

Misc.- UPS Mailing Costs

MO HealthNet Division
Sharp's Compliance (Medication Destruction Program)

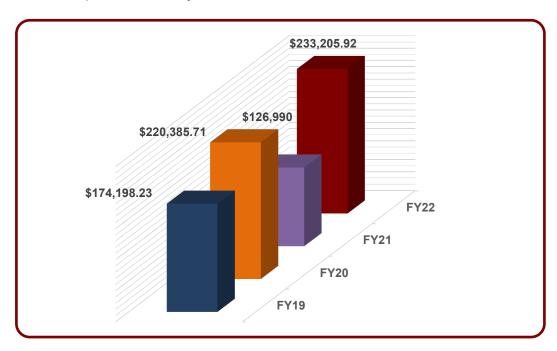
**Total Expenses** 

\$ 12,073.00	
\$ 25,000.00	
\$ 11,893.00	
\$ 6,247.91	
\$ 50,000.00	
\$ 17.01	
\$ 100,000.00	
\$ 27,975.00	
	\$ 233,205.92

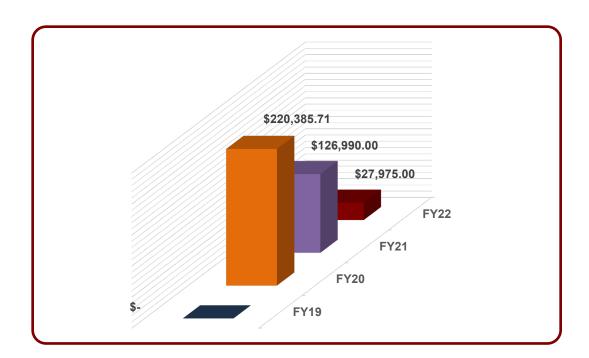
<sup>\*\*</sup> Grants awarded in FY 22 and expended grant funds will not be equal due to tiered payment schedules. Rx Cares funds may be awarded and expended in different fiscal years.



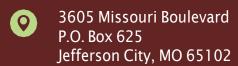
### Rx Cares Expenditures by FY



### **Rx Cares Medication Destruction Funding**



### BOARD OF PHARMACY





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